PHARMACY EXAMINING BOARD OCTOBER 28, 2009 MEETING MINUTES

PRESENT: Timothy Boehmer, R.Ph.; Amy Mattila, R.Ph; Jeanne Severson, R.Ph.; Pamela

Phillips; Jason Walker-Crawford, R.Ph.; Gregory C. Weber, R.Ph.

EXCUSED: Suzette Renwick

STAFF: Tom Ryan, Bureau Director; Ruby Jefferson-Moore, DRL Board Counsel;

Michelle Solem, Bureau Assistant; and other DRL Staff

GUESTS: Angela Schlagel, Ministry Health Care St. Joseph's Hospital; Angie Weitendorf

and Emma Hews, Aurora Health Care; Chris Gomez, Walgreens; Dean Polar, Cardinal Health; Phillip Olley, Pharmacy Students at University of Wisconsin – School of Pharmacy; Gina Besteman, Women's International Pharmacy; Dave Doane, Talyst/Roeschen's Omnicare Pharmacy; Gary Plank, Marshfield Clinic; Jamie Statz-Paynter, Dean Pharmacy; Paul Baum, Group Health Cooperative of South Central Wisconsin (GHC-SCW); Judy Warmuth, Wisconsin Hospital Association; Jeffrey Clinton and Mark Celebre, Roeschen's Omnicare Pharmacy; Michael Grebner, M.D., Medical Director MCSO; Tom Engels and Sarah Sorum, Pharmacy Society of Wisconsin (PSW); Lisa Sobotkiewicz, Target Pharmacy; Eric Knox, Department of Corrections (DOC) and Jo Preston,

Rural Wisconsin Health Cooperative (RWHC)

CALL TO ORDER

Gregory Weber, Board Chair, called the meeting to order at 9:02 a.m. A quorum of six members was confirmed.

APPROVAL OF AGENDA

Amendments:

- o Add Item F Pandemic Flu information-insert at pages 29-30
- o Add practice question after Item O page 74
- o Add 2 items between J & K
 - Variance Report from Community Memorial Hospital
 - Variance Request from Omnicare
- Add Item Q
 - Written comments from Greg Weber to the Legislature related to Pharmacists Dispensing Epilepsy Drugs
 - PEB Legislative Review Report
 - Assembly Bill 506
- o At the end of the agenda
 - Matthew Kolb Application Review.
- o Remove Item H Variance Request
- o Change pages for item O to pages 73-74
- o Remove Quality Review Council Report

- o Remove State Council on Alcohol and Other Drug Abuse Report
- Remove Report from National Association of Boards of Pharmacy Committee on Law Enforcement/Legislation Report and place on the Agenda for the February meeting
- o Remove Item S Re-registration Application Review

MOTION: Jason Walker-Crawford moved, seconded Amy Mattila, to approve the agenda as amended. Motion carried unanimously.

APPROVAL OF MINUTES OF SEPTEMBER 23, 2009

Corrections:

- Change Pamela Phillips from via phone to excused.
- Under amendments to the agenda:
 - Capitalize Item in "Strike item J"
 - Capitalize Item in "Defer item after O:

MOTION: Jeanne Severson moved, seconded by Jason Walker-Crawford, to approve the September 23, 2009 minutes as amended. Motion carried unanimously.

PRESENTATION OF PROPOSED STIPULATIONS

ECONOFOODS PHARMACY

No presentation was requested.

ELECTION OF OFFICERS

NOMINATION: Tim Boehmer nominated Jeanne Severson as chairperson.

The Chair called for additional nominations three times before calling the vote. Jeanne Severson was elected chairperson by

unanimous vote.

NOMINATION: Jeanne Severson nominated Amy Mattila as vice-chairperson.

Tim Boehmer nominated Jason Walker-Crawford as vicechairperson. The Chair called for additional nominations three times before calling the vote. Jason Walker-Crawford was elected

vice-chairperson by vote.

NOMINATION: Tim Boehmer nominated Pamela Phillips as secretary.

The Chair called for additional nominations three times before calling the vote. Pamela Phillips was elected secretary by

unanimous vote.

Pharmacy Examining Board October 28, 2009 Page 2 of 10 Greg Weber asked Board members to provide Jeanne Severson with feedback for the liaison positions. Tom Ryan indicated that requests have been made for 2 additional liaisons – a practice question liaison and a continuing education liaison. Greg Weber indicated that there were 2 appointments that could be eliminated – Examination Panel and PEB Case Development. The remaining appointments were deferred until the December meeting. Greg Weber asked the members to review the web-site as it relates to Pharmacy to suggest dated material that should be removed and also suggest additional information that could be added.

ADMINISTRATIVE REPORT

2010 Board Meeting Dates

The proposed schedule of meeting dates for 2010 was amended to change two meeting dates. The June meeting will change to June 2 and the December meeting will be held on December 15. There was also a request that teleconferences be avoided if at all possible.

MOTION: Jason Walker-Crawford moved, seconded by Jeanne Severson, to approve the 2010 Board meeting dates as amended. Motion carried unanimously.

Board Chair and Vice-Chair Training

Tom Ryan indicated that training for Board chairs and vice-chairs will occur on December 3 & 4. Jeanne Severson and Jason Walker-Crawford are invited to attend. Tim Boehmer asked if Amy Mattila can attend the training if either the chair or vice-chair would be unable to attend.

Practice Questions and FAQ's

Greg Weber appointed Jason Walker-Crawford and Amy Mattila to serve as practice question liaisons for the remainder of this year. Board members should forward any questions they answer along with any answer that was given to Tom Ryan (Thomas.Ryan@wisconsin.gov) and Ben Hanes (Ben.Hanes@wisconsin.gov). Tom Ryan will then disseminate the answers. Members will include a disclaimer indicating that any Board member response to a practice question is not legal advice provided by the Department and should not be relied on as such. If the Board member does not feel comfortable answering the question, they can refer people to the website or suggest that they seek an opinion of a private attorney.

Other

Ruby Jefferson-Moore announced her retirement effective November 20, 2009.

REPORT ON APPEARANCE AT LAKESHORE TECHNICAL COLLEGE TIM BOEHMER

No report was delivered. The appearance was canceled.

REPORT ON MPJE QUESTION REVIEW – OCTOBER 9-15, 2009 JEANNE SEVERSON

Jeanne Severson reported that the deadline was extended. She told the Board that there were 1000 new questions added and the current pool of questions was approximately 2500. Many new questions were rejected because they did not apply to Wisconsin.

DISCUSSION OF THE DEPARTMENT'S INITIATIVE TO CLOSE COMPLAINTS OPENED FOR INVESTIGATION WITHIN 18 MONTHS APPEARANCE – BRUCE CAMERON, DRL

Bruce Cameron reported that the Department will be working closer with the case advisors to close cases within 18 months. This is a goal of the Department based on information received from the various Boards that fall within the purview of the Department. The 18-month committee is asking the Board for support, ideas and feedback, which the Board provided.

SPEAKING ENGAGEMENT AND TRAVEL REQUESTS

None.

PANDEMIC FLU PREPAREDNESS – DISCUSSION OF POSSIBLE VARIANCES TO ADMINISTRATIVE RULES AND DRAFT LANGUAGE FOR DRL WEBSITE NOTICE

DISCUSSION RELATED TO POSSIBLE VARIANCE REQUESTS RELATED TO WIS. STAT. § 450.035

Jason Walker-Crawford asked that DHS be granted a variance under 450.035 (2) and (2) (g) to accommodate the need for additional vaccinations due to the pandemic. Currently, pharmacists are not allowed to administer vaccines to children under the age of 18. He stated that if the age limit is waived, there is an FDA approved vaccine and the pharmacist is properly trained, pharmacists should be able to administer the vaccine. Ruby Jefferson-Moore expressed a concern regarding legislative intent. Tim Boehmer described the rule associated with vaccinating children.

MOTION:

Jason Walker-Crawford moved, seconded by Jeanne Severson, that the Board encourage DHS to request a variance to Wis. Stats. 450.035 (2) and (2) (g) to waive the age requirement of 18 years for administration of flu vaccines during a pandemic declaration pursuant to 450.02 (3m). Motion carried unanimously.

WIS. STAT. § 450.02 (3M)

Greg Weber informed the Board that under Wis. Stats. 450.02 (3m), the Board has granted DHS an extension of its emergency variance. Greg Weber also suggested that a variance is needed for pharmacists and pharmacy students to provide vaccines for persons under 18 years of age. A letter to DHS will be drafted to encourage DHS to submit a variance request on behalf of all Wisconsin pharmacists and pharmacy students.

Gary Plank requested that the Board consider a variance waiving the requirement to dispense from a location that is licensed as a pharmacy to allow segregation of highly infectious people from the general public during a pandemic.

MOTION: Jeanne Severson moved, seconded by Amy Mattila, to authorize the Board

or its designee to grant variances on a case-by-case basis for the pandemic

flu for requests made using a variance request form.

Tim Boehmer will draft a statement for the website to inform licensees of this decision.

MARSHFIELD CLINIC REMOTE DISPENSING

<u>Variance Reports – April thru June 2009 – Lake Hallie, WI and Mercer, WI</u>

Gary Plank delivered his report. No concerns were noted.

Motion to Require Quarterly Reports

MOTION: Jason Walker-Crawford moved, seconded by Amy Mattila, to amend the

April 8, 2009 approved motion for variance for the Lake Hallie and Mercer locations of Marshfield Clinic Pharmacy to include submission of

calendar quarterly variance reports. Motion carried unanimously.

DELIVERY VARIANCE REQUEST MEDICAL CENTER PHARMACY MEDFORD, WI STACY SCHOEPKE

MOTION: Jason Walker-Crawford moved, seconded by Pamela Phillips, to deny the

variance request by the Medical Center Pharmacy as it does not include consultation before prescription leaves the pharmacy. HIPAA is not addressed, nor is there a procedure for the handling of prescriptions that

are not picked up or refused. Motion carried unanimously.

VARIANCE REQUEST FORMS – BOARD REVIEW AND APPROVAL APPEARANCE – KRIS HENDRICKSON

The remodel and the variance forms have been created with a reference to the form added to the instructions

The Board asked that the following changes be made to the variance instructions.

- Correct the zip code at the end of the first full paragraph.
- Capitalize Board throughout the document
- The second sentence of the paragraph beginning with "All variance requests..." should read "Submit requests at least 15 working days prior to the regularly scheduled meeting..." to be consistent within the instructions

The Board asked that the following changes be made to the variance form.

- Correct the spelling of Monthly in the first paragraph.
- Capitalize Board throughout the document
- Drop "Other" as a form of variance

MOTION: Jason Walker-Crawford moved, seconded by Jeanne Severson, to approve the variance form and instructions and remodel form and instructions subject to amendments. Motion carried unanimously.

Kris Hendrickson will create a new form for remote dispensing to be discussed at the February meeting with an effective date no earlier than April 1, 2010.

VARIANCE REPORTS – COMMUNITY MEMORIAL HOSPITAL OCONTO FALLS REMOTE DISPENSING SITES

Noted.

ROESCHEN'S OMNICARE PHARMACY VARIANCE REQUEST

Jeffrey Clinton, Mark Celebre, Michael Grebner, M.D., and Dave Doane appeared before the Board to present an automated dispensing variance request. Greg Weber and Ruby Jefferson-Moore indicated that because the rule specifically prohibits automated dispensing in correctional facilities, the Board does not have the authority to grant this variance. Greg Weber indicated that remote dispensing can occur in a correctional facility and therefore suggested that Roeschen's Omnicare Pharmacy might consider that avenue. Roeschen's Omnicare Pharmacy withdrew the request.

BOARD DISCUSSION OF ACCEPTABLE CONTINUING EDUCATION PROGRAMS WIS. ADMIN. CODE S. PHAR 16.03

The Board has only accepted ACPE courses up to this point in time. The Board decided not to consider alternative CE providers at this time. This agenda item may be on a future agenda.

WIS. ADMIN CODE S. PHAR 4.02 (2) RELATING TO THE PRACTICAL EXAMINATION - STATUS

Greg Weber indicated that this rule change will go in to effect on November 1, 2009

REMOTE DISPENSING – WIS. ADMIN. CODE S. PHAR 7.095 – RULE DRAFTING

Ruby Jefferson-Moore informed the Board that this rule has been sent to the Small Business Advisory Review Committee. The Department will be completing a fiscal estimate and forwarding the rule draft to the Clearinghouse for comments very soon. It is expected that the rule will be ready for public hearing at the December meeting. Public comments will be due no later than 4:30 p.m. on the day of the meeting.

Greg Weber indicated that the public could submit written and oral comments relating to this rule at the December meeting.

WIS. ADMIN. CODE S. PHAR 6.08, 7.12, 7.095 AND 8.12 RULE DRAFTING STATUS

The Board reviewed the rule drafts.

MOTION: Tim Boehmer moved, seconded by Amy Mattila, to approve the rule draft

amending Wis. Admin. Codes 6.08, 7.12 and 8.12 and send it to the

Legislative Clearinghouse. Motion carried unanimously.

MOTION: Tim Boehmer moved, seconded by Amy Mattila, to approve the rule draft

creating PHAR 7.095 and send it to the Legislative Clearinghouse.

Motion carried unanimously.

ELECTRONIC TRACK AND TRACE PEDIGREE SYSTEM AND BOARD RULES WIS. STAT. § 450.073 – WHOLESALE DISTRIBUTORS PEDIGREE - BOARD DISCUSSION

Ruby Jefferson-Moore indicated that she had received an inquiry from Department Information Technology staff related to their role in this process. The Board decided to revisit this topic at the February 3, 2010 meeting.

BOARD REVIEW OF CURRENT AND FUTURE RULEMAKING AND LEGISLATIVE INITIATIVES – DISCUSS AND SET PRIORITIES

Greg Weber reviewed an updated list of Board priorities. The Board provided its comments and asked that this list be a standing item on the agenda.

SUMMARY REPORTS ON ADMINISTRATIVE RULES

Tom Ryan reported on the status of the rules.

PRACTICE QUESTION – PHARMACY STUDENTS PERFORMING IMMUNIZATIONS AT A FLU CLINIC JANET GIFFORD – UNIVERSITY OF MINNESOTA – E-MAIL REQUEST

The Board determined that if a student attends an ACPE accredited college and received credit for an immunization class, that class is considered an ACPE accredited course and therefore a student taking that class can perform immunizations. The pharmacy student must meet all the other requirements of Wis. Stat. § 450.035.

PRACTICE QUESTION – DISPENSING IN PILL BOXES/BLISTER PACKAGING IN THE OUTPATIENT SETTING JEFFREY YOCHUM – E-MAIL REQUEST

The Board asked that Jeffrey Yochum be referred to the Consumer Product Safety Act, the Poison Prevention Packaging Act of 1970 and to the USP.

PRACTICE QUESTION – LICENSURE DISPLAY ARLENE IGLAR – E-MAIL REQUEST

The Board determined that this would be a reasonable alternative for displaying credentials.

REGULATORY DIGEST

No report at this time.

DOE INSPECTION LIAISON REPORT

No report at this time.

CREDENTIALING LIAISON REPORT

Tim Boehmer indicated that he is working on some items that he will bring to a future meeting.

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CLEAN SWEEP LEGISLATIVE DRAFT PROPOSAL AND DECISION

The Board reviewed drafts of possible legislative proposals that have been circulated for comment by other state government officials. No formal position was taken.

LEGISLATIVE LIAISON REPORT

AB 56

No action to report.

AB 227

The drug monitoring program bill has passed the Assembly and is now in the Senate. There is not yet a companion bill in the Senate.

AB 272 & SB 198

This bill has been passed in the Senate and is now in the Assembly.

AB 180

No action to report.

AB 482

This bill passed out of the Assembly Health Committee by executive action today.

DRUG ENFORCEMENT ADMINISTRATION MONTHLY DRUG THEFT AND LOSS REPORTS.

The Board reviewed the monthly theft and loss reports received from the Drug Enforcement Administration.

PUBLIC COMMENTS

None.

CLOSED SESSION

MOTION:

Jason Walker-Crawford moved, seconded by Jeanne Severson, to convene to closed session to deliberate on case(s) following hearing (Wis. Stat. § 19.85 (1) (a)); consider closing disciplinary investigation(s) with administrative warning(s) (Wis. Stat. § 19.85 (1) (b) and 440.205); to consider individual histories or disciplinary data (Wis. Stat. § 19.85 (1) (f)); and to confer with legal counsel (Wis. Stat. § 19.85 (1) (g)). Roll Call Vote: Timothy Boehmer-yes; Jeanne Severson-yes; Jason Walker-Crawford-yes; Gregory C. Weber-yes; Pamela Phillips-yes; Amy Mattila -yes. Motion carried unanimously.

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RECONVENE TO OPEN SESSION

MOTION: Jeanne Severson moved, seconded by Jason Walker-Crawford, to

reconvene into open session. Motion carried unanimously.

Open session reconvened at 2:44 p.m.

VOTING ON ITEMS CONSIDERED/DELIBERATED IN CLOSED SESSION APPLICATION REVIEW – MATTHEW J. KOLB – CHICAGO, IL

No action required.

PROPOSED STIPULATIONS, FINAL DECISIONS AND ORDERS

ECONOFOODS PHARMACY

MOTION: Jason Walker-Crawford moved, seconded by Amy Mattila, to adopt the

Findings of Fact, Conclusions of Law, Stipulation and Order, in the matter

of Econofoods Pharmacy. Motion carried unanimously.

CASE CLOSINGS

09 PHM 029

MOTION: Tim Boehmer moved, seconded by Amy Mattila, to close case 09 PHM

029 for insufficient evidence. Motion carried unanimously.

ADJOURNMENT

MOTION: Jeanne Severson moved, seconded by Jason Walker-Crawford, to adjourn

the meeting at 2:46 p.m. Motion carried unanimously.